K140924

JUN 0 5 2014

510(k) SUMMARY

H.C. Starck Ceramics GmbH
StarCeram®

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Maureen O'Connell
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Date Prepared: March 21, 2014

Name of Device and Name/Address of 510(k) Owner

StarCeram® Z-Med
StarCeram® Z-Al-Med HD
StarCeram® Z-Al-Med HD Colour
StarCeram® Z-Al-Med-HD Translucent
StarCeram® Z-Med TransColour
StarCeram® Z-Med TransColour Red

H.C. Starck Ceramics GmbH
Lorenz-Hutschenreuther-Str. 81
95100 Selb, Germany

Common or Usual Name

Powder, Porcelain

Classification Name

21 C.F.R. 872.6660

Predicate Devices

StarCeram Z-Med and Z-Al-Med HD (K133213)

Intended Use / Indications for Use

Dental Blanks made from StarCeram® are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include both anterior and posterior bridges.

Technological Characteristics

Dental blanks made from StarCeram® products are semi finished products made of yttrium stabilized pre-sintered zirconium dioxide for milled production of crowns and bridge framework on commercial CAD/CAM systems or hand-operated copy-milling. StarCeram® Z-Med TransColour Red is a modification to the StarCeram® products that have already been cleared by the Food and Drug Administration in K133213. StarCeram® Z-Med TransColour Red has the same intended use and fundamental scientific technology as the StarCeram® products previously cleared by FDA. The only change is the addition of a new color additive.

Performance Data

No performance data was required or provided. Biocompatibility and cytotoxicity testing was performed which showed that all versions of the product comply with ISO 10993-1 and ISO 10993-5. Biocompatibility testing was performed under Design Controls to show that the modified version of the product continued to comply with the recognized consensus standards.

Substantial Equivalence

H.C. Starck's StarCeram® Z-Med Transcolour Red is a modification to the StarCeram® products cleared in K133213. StarCeram® Z-Med TransColour Red has the same intended use and indications for use, principles of operation, and similar technological characteristics as the previously cleared predicate device. StarCeram® Dental Blanks are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include anterior and posterior bridges. This is the exact indications for use statement cleared for StarCeram® in K133213. Thus, StarCeram® Z-Med TransColour Red has the same intended use and may be substantially equivalent.

StarCeram® Z-Med TransColour Red has the same technological characteristics as the predicate device. All of the devices are yttrium stabilized pre-sintered zirconium dioxide to be used in dental restorations. The StarCeram® products cleared in K133213 and StarCeram® Z-Med TransColour Red are all dental blanks which are fabricated to the desired shape by the user based on the specific needs of the patient. The only

difference between StarCeram® Z-Med TransColour Red and the StarCeram® products cleared in K133213 is the addition of a color additive.

This difference has been addressed by performing biocompatibility testing which shows that the new version of the product was found to be biocompatible. Therefore, the differences do not affect the safety or effectiveness of the products.

Indications for Use Statement

510(k) Number (if known): K140924

Device Name: StarCeram®

Indications for Use:

Dental Blanks made from StarCeram® are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include both anterior and posterior bridges.

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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_____ _____ _____ _____
_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 5, 2014

H.C. Starck Ceramics GmbH
C/O Ms. Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Incorporated
5 Timber Lane
North Reading, MA 01864

Re: K140924
Trade/Device Name: StarCeram® Z-Med TransColour Red
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 8, 2014
Received: May 9, 2014

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140924

Device Name: StarCeram®

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(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807
Subpart C)

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